

# Notice of Allowability

Application No.

09/489,394

Examiner

Sean E. Aeder, Ph.D.

Applicant(s)

HSEI ET AL.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to a telephone conversation with applicant on July 15, 2005.
2. ☒ The allowed claim(s) is/are 124-145.
3. ☒ The drawings filed on 21 January 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|   | 9. <input type="checkbox"/> Other _____   |

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with James Fox on July 15, 2005 at 3:00pm EST.

The following claims were amended:

124. (currently amended) A conjugate consisting essentially of an antibody fragment covalently modified by one or two nonproteinaceous polymer molecules at a free sulfhydryl group of a cysteine residue within the hinge region of the antibody fragment, wherein a disulfide bridge within the hinge region is avoided by substituting another amino acid for the corresponding cysteine residue within the hinge region in the opposite chain of said antibody fragment, and wherein (a) the apparent molecular weight of the conjugate, as determined by size exclusion chromatography, is at least about 500 kD, (b) the average actual molecular weight of each nonproteinaceous polymer molecule is at least 20 kD, and (c) the conjugate has an apparent size that is at least about 8-fold greater than the apparent size of the parental antibody fragment, and

(d) the conjugate binds the same antigen as the parental molecule that is not covalently modified by one or two nonproteinaceous polymer molecules.

133. (currently amended) A conjugate consisting essentially of an antibody fragment covalently modified by two nonproteinaceous polymer molecules at a free sulfhydryl group of a cysteine residue within the hinge region of the antibody fragment, wherein a disulfide bridge within the hinge region is avoided by substituting another amino acid for the corresponding cysteine residue within the hinge region in the opposite chain of said antibody fragment, and wherein (a) the apparent molecular weight of the conjugate, as determined by size exclusion chromatography, is at least about 500 kD, (b) the average actual molecular weight of each nonproteinaceous polymer molecule is at least 20 kD, and (c) the conjugate has an apparent size that is at least about 8-fold greater than the apparent size of the parental antibody fragment, and (d) the conjugate binds the same antigen as the parental molecule that is not covalently modified by two nonproteinaceous polymer molecules.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

  
**GARY B. NICKOL, PH.D.**  
**PRIMARY EXAMINER**